REMARKS

Applicants appreciate the Examiner's thorough consideration provided the present application. Claims 1, 28-31 and 33-47 are now present in the application. Claims 1 and 38 have been amended. Claims 1 and 38 are independent. Reconsideration of this application, as amended, is respectfully requested.

Claim Objections

Claims 1 and 23-36 [sic., claims 1, 28-31 and 33-36] stand objected to due to the presence of minor informalities. In view of the foregoing amendments, it is respectfully submitted that this objection has been addressed. Accordingly, Applicants respectfully submit that this objection has been obviated and/or rendered moot. Reconsideration and withdrawal of this objection are respectfully requested.

Claim Rejections Under 35 U.S.C. §112

Claims 1 and 23-36 [sic., claims 1, 28-31 and 33-36] stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. This rejection is respectfully traversed.

In view of the foregoing amendments, it is respectfully submitted that this rejection has been addressed. Accordingly, all pending claims are now definite and clear. Reconsideration and withdrawal of the rejection under 35 U.S.C. § 112, second paragraph, are therefore respectfully requested.

Claim Rejections Under 35 U.S.C. § 103

Claims 1, 28-31 and 33-47 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Ellingsen, WO 95/17217, optionally in view of Steinemann, U.S. Patent No. 5,456,723 and Haruyuki, JP 3146679. This rejection is respectfully traversed.

A complete discussion of the Examiner's rejection is set forth in the Office Action, and is not being repeated here.

While not conceding to the Examiner's rejection, but merely to expedite prosecution, as the Examiner will note, independent claims 1 and 38 have been amended.

Independent claim 1 now recites a combination of elements including "treating the metallic implant surface with an aqueous solution of hydrofluoric acid, resulting in an etching process, wherein the concentration of the hydrofluoric acid is less than 0.5 M, and wherein the metallic implant surface is treated for an etching period of up to 180 seconds at room temperature, said etching period being measured from the formation of the first bubble of H_2 (g) at the implant surface, thereby providing an oxide layer with fluorine and/or fluoride incorporated therein and distributed throughout the oxide layer on at least a part of the implant surface, and providing a microroughness comprising pores having a pore diameter within a range of 1 nm to 1 μm and a pore depth within a range of 1 nm to 500 nm."

Independent claim 38 now recites a combination of elements including "the implant surface is a metallic implant surface, there is an oxide layer on at least part of the implant surface, said oxide layer having fluorine and/or fluoride incorporated therein, and at least a part of the implant surface comprises a microroughness which comprise pores having a diameter within a range of 1 nm to 1 μm and a pore depth within a range of 1 nm to 500 nm, wherein the

microroughness comprises peaks having a peak width, at half the pore depth, of from 15 to 150% of the pore diameter."

Support for the amendments to claims 1 and 38 can be found on page 7, lines 34-37 and page 15, lines 19-21 of the specification as originally filed. Applicants respectfully submit that the combinations of elements set forth in claims 1 and 38 are not disclosed or suggested by the references relied on by the Examiner.

Claim 1

One major difference between the claimed invention as set forth in claim 1 and the disclosure of Ellingsen is that claim 1 is directed to etching of the implant surface, while Ellingsen clearly teaches that no significant etching shall occur. As a result, the claimed invention as set forth in claim 1 leads to a surface structure which is completely different from the structure obtained by Ellingsen. More specifically, the method as recited in claim 1 provides:

- an oxide layer with fluorine and/or fluoride incorporated therein and distributed throughout the oxide layer on at least part of the implant surface, and
- a microroughness comprising pores having a pore diameter within the range of 1 nm to 1 μm, and a pore depth within the range of 1 nm to 500 nm.

The Examiner alleged that Ellingsen et al uses implants having a minimal natural oxide layer, and consequently the chemical reaction between the titanium and HF would occur relatively quickly. In addition, the Examiner also stated that the "formation of the first bubble" test seems fairly subjective. Applicants respectfully disagree.

In particular, the fact that Ellingsen indicates that the treated implants are removed from sterile packaging and placed in the HF treatment bath is no evidence whatsoever for a minimal

natural oxide layer being present on the implant surface. On the contrary, due to the sterilisation method used, there is most likely a significant oxide layer present on the implant surface.

More specifically, the HF treatment according to Ellingsen is performed on implants which had been sterile packaged and autoclaved at 120 °C for 30 minutes (see e.g. page 10, lines 4-6). This heat treatment during sterilisation increases the thickness of the oxide layer, since the growth of the oxide layer is favored by heat. Therefore, the sterilisation treatment used by Ellingsen actually leads to implants having a thick oxide layer. This oxide layer is present on the implant surface when the implants are removed from the sterile packaging and placed in the HF treatment bath.

Therefore, it is very likely that an oxide layer is indeed present during the whole period during which HF treatment occurs, and consequently, there is no etching of the metallic surface. This is also confirmed by the clear teaching of Ellingsen that no etching of the implant surface occurs during the HF treatment.

With regard to the alleged subjectivity of the etching period as defined in claim 1, Applicants respectfully submit that the establishment of the point in time when the first bubble of $H_2(g)$ at the implant surface is formed can be determined very precisely by potentiometric measurement, which would immediately be recognized by one of ordinary skill in the art. Therefore, it is not a subjective test as the Examiner alleged.

In addition, as recited in claim 1, the pore diameter is within the range of 1 nm to 1 μm, and the pore depth is within the range of 1 nm to 500 nm. Therefore, claim 1 is delimited from the insignificant and non-desired nano-etching that allegedly occurs in Ellingsen.

Claim 38

One major difference between the claimed invention as set forth in claim 38 and the disclosure of Ellingsen is that claim 38 is directed to very specific microroughness parameters, and also that there is an oxide layer having fluorine and/or fluoride incorporated therein on the implant surface.

This specific surface morphology gives a very resistant bone in-growth. With this specific morphology, newly formed bone, which grows into the surface irregularities of the implant surface, does not easily fracture from the old bone. In addition, the peaks of the implant surface do not easily fracture from the implant. In addition, the fluorine and/or fluoride incorporated within the oxide layer on the metallic implant surface make the oxide layer more reactive than an oxide layer without fluorine and/or fluoride (see the Examples in the specification). For example, a titanium oxide with incorporated fluorine and/or fluoride has a disturbed oxide structure as compared to an ordinary pure titanium oxide structure. Without being bound by any theory, the disturbed oxide structure gives a more reactive oxide layer, which means that the oxide in vivo probably to a higher degree, as compared to a pure titanium oxide structure, interacts with molecules, such as phosphate ions, and probably also grows at a higher rate, which means that an improved biocompatibility is attained.

The superiority of the implants according to the invention is shown by the examples provided in the application. With reference to Table 1 on page 21 of the specification as originally filed, it can be seen that the implants according to the invention gave an improved bone attachment as compared to the implants according to Ellingsen.

In great contrast, Ellingsen is completely silent about any specific surface parameters, and simply teaches, without wishing to be limited to the expression of theories, that the improved

biocompatibility is thought to be due to fluoride ions being retained on the surface of the implant.

In addition, as recited in claim 38, the pore diameter is within the range of 1 nm to 1 μm, and the pore depth is within the range of 1 nm to 500 nm. Therefore, claim 38 is delimited from the insignificant and non-desired nano-etching that allegedly occurs in Ellingsen.

Furthermore, for the same reasons as described on page 14, line 2 – page 16, line 15 and page 17, line 21 – page 18, line 12 of the Amendment dated October 13, 2009, neither Steinemann nor Haruyuki would lead a person skilled in the art in the direction of the present invention.

Accordingly, none of the utilized references individually or in combination teach or suggest the limitations of amended independent claims 1 and 38. Therefore, Applicants respectfully submit that amended independent claims 1 and 38 clearly define over the teachings of the utilized references.

In addition, claims 28-31, 33-37 and 39-47 depend, either directly or indirectly, from independent claims 1 and 38, and are therefore allowable based on their respective dependence from independent claims 1 and 38, which are believed to be allowable.

In view of the above remarks, Applicants respectfully submit that claims 1, 28-31 and 33-47 clearly define the present invention over the references relied on by the Examiner.

Accordingly, reconsideration and withdrawal of the rejection under 35 U.S.C. § 103 are respectfully requested.

CONCLUSION

All the stated grounds of rejection have been properly traversed and/or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently pending rejections and that they be withdrawn.

It is believed that a full and complete response has been made to the Office Action, and that as such, the Examiner is respectfully requested to send the application to Issue.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Craig A. McRobbie (Reg. No. 42,874) at the telephone number of the undersigned below.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. §§ 1.16 or 1.17; particularly, extension of time fees.

Dated: May 19, 2010

Respectfully submitted,

By #61007

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